



PTO/SB/21 (08-03)  
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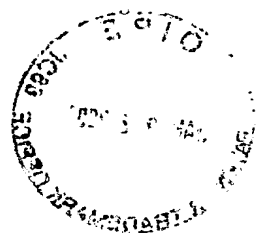
<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/673,629	
	Filing Date	September 29, 2003	
	First Named Inventor	Hector F. DeLuca	
	Art Unit	1616	
	Examiner Name		
Total Number of Pages in This Submission	57	Attorney Docket Number	1256-00923

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <b>Return Receipt Postcard</b>
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>		
Firm or Individual name	Thomas M. Wozny, Reg. No. 28,922 Andrus, Seales, Starke & Sawall, LLP	
Signature		
Date	January 19, 2004	

CERTIFICATE OF TRANSMISSION/MAILING	
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.	
Typed or printed name	Dorothy A. Hauser
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Date	January 19, 2004

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant :	Hector F. DeLuca et al	)	I hereby certify that this correspondence
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		)	
TC/A.U. :	1616	)	
Examiner :		)	 January 19, 2004
		)	Dorothy A. Hauser Date
Docket No. :	1256-00923	)	

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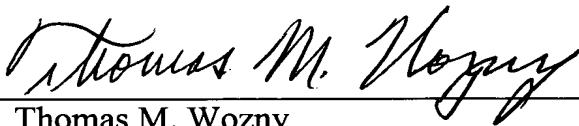
Sir:

The references listed on the enclosed PTO Form 1449 are being submitted in the above-identified patent application in accordance with 37 CFR 1.97(b)(3).

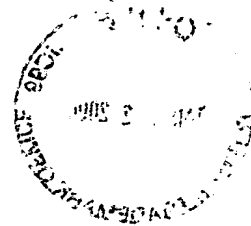
A copy of each of the listed references is enclosed in compliance with the rules.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By   
Thomas M. Wozny  
Reg. No. 28,922

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/673,629
Filing Date	September 29, 2003
First Named Inventor	Hector F. DeLuca
Art Unit	1616
Examiner Name	
Attorney Docket Number	1256-00923

Sheet	1	of	3
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## U. S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

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		Application Number	10/673,629
		Filing Date	September 29, 2003
		First Named Inventor	Hector F. DeLuca
		Art Unit	1616
		Examiner Name	
Sheet 2	of 3	Attorney Docket Number	1256-00923

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		The Merck Manual, Sixteenth Edition, 1992, pg. 1357.	
		Boris et al, "Relative Activities of Some Metabolites and Analogs of Cholecalciferol in Stimulation of Tibia Ash Weight in Chicks Otherwise Deprived of Vitamin D," Vitamin D Metabolites, Analogs and Bone Ash, 1976, pp. 194-198.	
		Hedlund et al, "Increased Incidence of Hip Fracture in Osteoporotic Women Treated with Sodium Fluoride," Journal of Bone and Mineral Research, Vol. 4, No. 2, 1989, pp. 223-225.	
		Holick et al, Harrison's Principle of Internal Medicine, 13th Ed. 1994, pp. 2137-2151.	
		Jensen et al, "Treatment of Post Menopausal Osteoporosis, A Controlled Therapeutic Trial Comparing Oestrogen/Gestagen, 1,25-Dihydroxy-Vitamin D-3 and Calcium," Clinical Endocrinology, 16, 1982, pp. 515-524	
		Meunier, "Evidence-Based Medicine and Osteoporosis: A Comparison of Fracture Risk Reduction Data from Osteoporosis Randomised Clinical Trials," IJCP, Vol. 53, No. 2, March, 1999.	
		Nordin et al, "The Metabolic Basis of Osteoporosis," Osteoporosis: Physiological Basis, Assessment, and Treatment, Elsevier Science Publishing Co., Inc., 1990, pp.23-36.	
		Ott et al, "Calcitriol Treatment is not Effective in Postmenopausal Osteoporosis," Annals of Internal Medicine, Vol. 110, No. 4, February 15, 1989, pp. 267-274.	
		Peck, "The Pathogenesis of Postmenopausal Osteoporosis," Osteoporosis: Physiological Basis, Assessment, and Treatment, Elsevier Science Publishing Co., Inc., 1990, pp. 3-6.	
		Riggs et al, "Bone Turnover Matters: The Raloxifene Treatment Paradox of Dramatic Decreases in Vertebral Fractures without Commensurate Increases in Bone Density," Journal of Bone and Mineral Research, Vol. 17, No. 1, 2002, pp. 11-13.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		<b>Application Number</b>	
		<b>Filing Date</b>	
		<b>First Named Inventor</b>	
		<b>Art Unit</b>	
		<b>Examiner Name</b>	
<b>Attorney Docket Number</b>			
Sheet	3	of	3

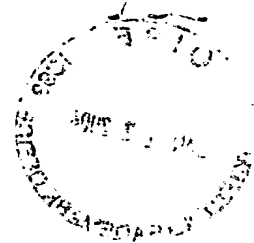
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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Riggs et al, "Causes of Age-Related Bone Loss and Fractures," Osteoporosis: Physiological Basis, Assessment, and Treatment, 1990, pp. 7-16.	
		Christensen, Abstract PMID: 6795047, "Effect of 1,25-Dihydroxy-Vitamin D3 in Itself or Combined with Hormone Treatment in Prevent Postmenopausal Osteoporosis," Eur. J. Clin. Invest., August 11, 1981, Vol. 11, No. 4.	
		Klein, "Nutritional Rickets and Osteomalacia," Primer on the Metabolic Bone Diseases and Disorders of Mineral Metabolism, 1996, pp. 301-305.	
		Kleerekoper, "Treatment of Osteoporosis with Sodium Fluoride Alternating with Calcium and Vitamin D," Osteoporosis: Recent Advances in Pathogenesis and Treatment, 1981, pp. 441-448.	
		Sarkar, "Relationships Between Bone Mineral Density and Incident Vertebral Fracture Risk with Raloxifene Therapy," Journal of Bone and Mineral Research, Vol. 17, No. 1, 2002, pp. 1-10.	
		Cummings et al, "Improvement in Spine Bone Density and Reduction in Risk of Vertebral Fractures During Treatment with Antiresorptive Drugs," The American Journal of Medicine, Vol. 112, 2002, pp. 281-289.	
		Sudhaker Rao et al, "Metabolic Bone Disease in Gastrointestinal Hepatobiliary, and Pancreatic Disorders," Primer on the Metabolic Bone Diseases and Disorders of Mineral Metabolism, 1996, pp. 306-311.	
		Watts et al, "Intermittent Cyclical Etidronate Treatment of Postmenopausal Osteoporosis," The New England Journal of Medicine, Vol. 323, No. 2, July 12, 1990, pp. 73-79.	
		Harris, "Four-Year Study of Intermittent Cyclic Etidronate Treatment of Postmenopausal Osteoporosis: Three Years of Blinded Therapy Followed by One Year of Open Therapy," The American Journal of Medicine, Vol. 95, December 1993, pp. 557-567.	

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